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REMARKS

Claims 10 and 11 have been canceled without prejudice or

disclaimer. Claims 1 and 4 have been amended, and new claims 14

and 15 have been added. Upon entry of these amendments, Claims 1-

9 and 12-15 will be pending, of which claims 6-9 and 12-13 are

withdrawn as directed to non-elected subject matter.

Amendments to the Claims

Claims 1 and 4 have been amended to remove reference to

precursors and derivatives, and reformatted by removing commas

that are inconsistent with the revised structure of these claims.

Claims 1 and 4 also have been amended to recite that the

administration is performed orally. This is supported in the

original specification for a pharmaceutical composition at page 8,

line 5. A food is implicitly understood to be administered

orally.

Claims 1 and 4 further have been amended to recite that the

step of administration is to a bird or mammal whose intestinal

flora is out of balance. Support for this amendment is found in

the original specification at page 6, lines 14-21. In that

passage, an improvement of the intestinal flora is defined as

either (1) a change of the composition of the intestinal flora

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whereby the proportion in the population of harmful bacteria is

reduced, or (2) as stabilization of the intestinal flora in a

condition in which it is in balance. Thus, the definition refers

to either (1) changing the composition when the intestinal flora

is out of balance or (2) stabilizing the composition when it is in

balance. These are two complementary conditions, and implicitly

either one or the other must be true. While the passage does not

explicitly state that condition (1) refers to the flora as being

"out of balance", such is implicitly the meaning of the passage,

because it is contrasted with condition (2), where the passage

explicitly states that the flora is "in balance". The passage

therefore describes two alternative methods, the first being a

rectification of an intestinal flora that is out of balance, and

the second being a stabilization of an intestinal flora that is in

balance. The state of the intestinal flora of being out of

which corresponds to an excess proportion of

population represented by harmful bacteria, is what is being

addressed by the methods of claims 1 and 4.

The specification further explains what is meant by the

condition where the intestinal flora is out of balance in the

immediately following passage, at page 6, lines 22-27, which

provides support for new claims 14 and 15. The passage states

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that harmful bacteria are associated with diarrhea, infections of

the gastrointestinal tract, liver damage, and/or intestinal

The passage also states that useful bacteria promote, and

by implication harmful bacteria inhibit, stimulating immunological

functions, reducing problems resulting from distention due to gas,

improving digestion, absorption of nutrients, and synthesis of

vitamins. Therefore, this passage supports the new claims, which

recite administering the food or pharmaceutical composition to a

bird or mammal suffering from one or more of diarrhea,

infection of the gastrointestinal tract, liver damage, intestinal

cancer, poor immunological function, distension due to gas, poor

digestion, poor absorption of nutrients, and vitamin deficiency.

No new matter has been added.

Rejection Under 35 U.S.C. §§ 101 and 112, Second Paragraph

Claims 10-11 are rejected as being indefinite and as reciting

non-statutory subject matter. Claims 10-11 have been canceled,

rendering the rejection moot.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-5 are rejected as allegedly lacking enablement over

their full scope. The rejection is respectfully traversed.

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The rejection refers to the step of administration, which is

not limited to any particular route of administration, and is

therefore allegedly not enabled over the full scope. The Examiner

has stated, however, that the claims are enabling for oral

administration. The claims have been amended to limit the

administration to oral administration. Therefore, the present

claims are believed to be fully enabled, and withdrawal of the

rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-5 are rejected as allegedly indefinite for reciting

"improving the composition of the intestinal flora" and for

reciting "precursor" and "derivative" with respect

sphingolipids. The rejection is respectfully traversed.

The recitation of precursors and derivatives has been deleted

from the claims, rendering that part of the rejection moot.

As to "improving the composition of the intestinal flora",

this term is defined in the specification at page 6, lines 14-27.

The specification specifically defines this phrase as referring to

either "a change of the intestinal flora of a bird or mammal,

whereby the proportion in the population of harmful bacteria is

reduced" or "stabilization of the flora in a condition in which it

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The present amendments of claims 1 and 4 have is in balance".

further clarified that the claimed methods are directed to such

improvements where the intestinal flora is out of balance, i.e.,

where there is an excess proportion of the population represented

by harmful bacteria. Therefore, it would be clear to the ordinary

skilled person, based on the language of the claims in view of the

specification, that the claims refer to a method of improving the

composition of the intestinal flora wherein the improvement takes

the form of reducing the proportion of harmful bacteria in the

intestinal flora.

The specification further clarifies what is meant by "harmful

bacteria" at page 6, lines 17-27. First, it is pointed out that

the skilled person is aware of species of bacteria that are

generally known to be healthy for the intestinal flora (such as

Lactobacillus and Bifidobacterium spp.) as well as species that

are known to be harmful (such as Clostridium difficile). Examples

are also provided of conditions that are associated with harmful

bacteria (diarrhea, gastrointestinal infections, liver damage, and

intestinal cancer) and conditions associated with healthy bacteria

(such as inhibition of the growth of harmful bacteria, stimulation

of immune function, reduction of bloating, improved digestion and

absorption of nutrients, and vitamin synthesis).

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Thus, the specification makes clear what is meant by harmful

bacteria and their overgrowth in the intestinal flora, and the

phrase "improving the composition of the intestinal flora"

clear and definite. The withdrawal of the rejection

respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 4 are rejected as allegedly anticipated by US

6239297 ('297). The rejection is respectfully traversed.

The rejection alleges that '297 discloses oral administration

of sphingosine derivatives. The rejection continues by

acknowledging that '297 fails to teach any effects of the

sphingosine derivatives on the intestinal flora, but argues that

such effects would have been inherent.

Applicants' present claims specify, however, that

sphingolipid is orally administered to a specific set of subjects,

namely subjects whose intestinal flora is out of balance. Because

oral administration of a sphingolipid to this set of subjects is

not disclosed in '297, the claimed method is distinct from and

patentably novel over the method of '297. The claimed method is

not inherent to the method of '297, because '297 does not teach or

suggest any particular disease or condition that is treated by

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oral administration of the disclosed sphingosine derivatives. For

the same reason, the claimed method is also non-obvious over '297,

which does not in any way point toward the set of avian or

mammalian subjects treated in the presently claimed method.

The withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-4 are rejected as allegedly obvious over WO 0234062

(WO '062). The rejection is respectfully traversed.

WO '062 is cited as teaching that sphingomyelin plays an

important role in food chemistry and in communication between and

within cells. The rejection admits that WO '062 fails to

appreciate any effects of sphingomyelin on improving

intestinal flora, but alleges that this feature would be inherent

to sphingomyelin administration.

The WO '062 application, like the '297 patent discussed in

the previous section, completely fails to teach or suggest the

administration of sphingomyelin to the group of subjects recited

in the present claims, namely a bird or mammal whose intestinal

flora is out of balance. Therefore, the present claims are not

obvious over the WO '062 application, and the rejection should be

withdrawn.

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Claims 1 and 4-5 are rejected as allegedly obvious over US

6610835 ('835). The rejection is respectfully traversed.

The '835 patent is cited as teaching certain sphingolipids as

modulators of neoplastic transformation and suppressors of

carcinogenesis, and as recognizing that only small amounts of

orally administered sphingolipids survive to the lower intestine,

and consequently as recognizing a need to increase bioavailability

of orally administered sphingolipids. Not surprisingly, the

object of the '835 patent is to provide prodrugs of sphingolipids

so as to decrease their selective cleavage in the lower GI tract

and thereby increase their bioavailability. See, e.g., '835 at

col. 9, lines 37-40.

The Examiner has concluded that the poor survival of

sphingolipids to the lower GI tract is motivation to simply boost

the level of sphingolipids by a mechanism similar to that of the

present invention. However, this is not proposed in the '835

patent, which instead pursues an entirely different approach--that

of synthesizing pro-drugs of sphingolipids. Indeed, the poor

survival of sphingolipids in the lower GI tract, as pointed out by

the Examiner, should be seen as teaching away from the present

invention, not as rendering it obvious. Poor survivability of

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sphingolipids in the GI tract would seem to cast doubt as to

whether sufficient levels of sphingolipid would survive to the

lower GI tract to be effective. At a minimum, the selective

cleavage of sphingolipids in the lower GI tract

unpredictable whether the object of the present invention could be

achieved.

Regardless of the relevance of the observation in '835

concerning survivability of sphingolipids in the lower GI tract,

the '835 patent completely fails to teach or suggest the oral

administration of sphingolipids to a set of avian and mammalian

subjects whose intestinal flora is out of balance. Therefore, the

claims are not obvious over '835, and the rejection should be

withdrawn.

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The Examiner is encouraged to telephone the undersigned

attorney to discuss any matter that would expedite allowance of

the present application.

Respectfully submitted,

Willem Ferdinand Nieuwenhuizen

Dated: October 22, 2010

By:/Charles L. Gagnebin iii/

Charles L. Gagnebin III Registration No. 25,467

Attorney for Applicant(s)

bgagnebin@wsglip.com

WEINGARTEN, SCHURGIN,

GAGNEBIN & LEBOVICI LLP

Ten Post Office Square

Boston, MA 02109

Telephone: (617) 542-2290

Telecopier: (617) 451-0313

CLG/LJH/mrb

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